UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,869	09/23/2003	Cyrus Rustam Kumana	V9661.0072	5138

32172 7590 02/07/2007

DICKSTEIN SHAPIRO LLP
1177 AVENUE OF THE AMERICAS (6TH AVENUE)
NEW YORK, NY 10036-2714

EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,869	KUMANA ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3,7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/24029.

WO 99/24029 expressly discloses a composition containing arsenic trioxide, water, NaOH and HCl (Pg. 27, lines 20-38).

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The claims are directed to a composition. The intended use of the composition does not patentably distinguish the prior art composition form the prior art. The Applicant has provided no evidence that the prior art composition cannot be administered orally. With respect to the process limitations in the composition claim, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product

in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The Applicant has provided no evidence that the prior art product is different from the claimed invention.

Claims 1-3,7,8 are rejected under 35 U.S.C. 102(a) as being anticipated by CN1370540 (Abstract).

CN1370540 (Abstract) expressly discloses a composition containing arsenic trioxide, water, NaOH and HCl.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the same reasons as above.

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24029 and CN1370540.

WO 99/24029 disclose treatment of leukemia with neutralized solution containing arsenic trioxide, NaOH and HCl (WO 99/24029, see entire document, especially, Pg. 14, lines 18-38, Pgs. 15-41, Claims 16-18). It is disclosed that the composition can be administered orally (Page 17, lines 14-34).

CN1370540 disclose treatment of leukemia with neutralized solution containing arsenic trioxide, NaOH and HCl (CN1370540, Abstract).

The prior art discloses treatment of leukemia with neutralized solution containing arsenic trioxide, NaOH and HCl that can be administered orally. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose using specified amounts of arsenic trioxide, water, HCl and NaOH and specific method of preparation.

However, the prior art discloses similar solutions which are used for treatment of leukemia having a neutralized pH and containing NaOH and HCl. As such, it would have been well within the skill in the art to very the steps and concentrations of NaOH and HCl added so long as the final solution is at neutralized pH, with the expectation the final solution would be suitable in the treatment of leukemia. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). See also In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003)("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). See also Ex parte Rubin , 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated

with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for same reasons as above, and the further reason below.

Contrary to the Applicant's arguments, as indicated above, WO'029 does disclose oral administration. Further, as indicated above, the end product is obvious and it is prima facie obvious to select any order of performing process steps absent new or unexpected results. Since the Applicant has not provided any evidence that the steps used in preparing the arsenic trioxide solution result in new or unexpected results, the rejection is maintained as to the composition and method of making claims. WO '029 does not teach away from the claimed invention as, as indicated above, said reference clearly discloses that the composition can be orally administered. The mere fact that the reference also discloses administration by intravenous injection is not sufficient to overcome the rejection. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Since the prior art does teach oral administration of arsenic trioxide for treatment of leukemia, contrary to the Applicant's arguments, there is a reasonable expectation of success.

The Applicant submits a reference by Siu et al. as evidence of unexpected activity, however, evidence of unexpected activity must be by affidavit or declaration. See Ex parte Gray, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989) ("The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001." Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute.). The Siu et al. reference as described by the Applicant appears to be directed to the difference in the effect of intravenous administration versus oral administration on the heart. Claims 1-27 are directed to compositions and methods of preparing compositions. Since the reference does not show that the components of the composition or process by which the composition is prepared resulted in the difference in activity, the reference is not sufficient to overcome the rejection of claims 1-27.

Claim 28-42 are directed to a methods of using the arsenic trioxide to treat hematological malignancies. The Applicant has argued that oral administration provided unexpected activity versus intravenous administration. However, only claim 37 is directed to oral administration. As such, the Siu et al. reference is only relevant to claim 37. The study in Siu et al. involved 16 patients with acute promyelocystic leukemia treated with oral arsenic trioxide and lacked a control study with intravenous patients (Siu et al., pages 6, 11). The reference concludes that oral arsenic trioxide "may be the preferred formulation for prolonged arsenic treatment" (Siu et al., pg. 11). Claim 37 is not limited to treatment of acute promyelocystic leukemia. As such, in view of the fact that the evidence submitted is not by way of affidavit or declaration; the reference did not disclose a direct comparison with patients intravenously administered arsenic trioxide under the same or comparable conditions; that the prior art does disclose oral

administration and the breadth of the claim; the Siu et al. reference is not commensurate in scope with the invention set forth in claim 37 and is not sufficient to overcome the rejection over the prior art.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
February 1, 2007

Johann Richter, Ph. D. Esq.
Supervisory Patent Examiner
Technology Center 1600